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DATE MAILED:

| APPLICATION NO. | FILING DATE | FIRST NAMED I | NVENTOR | | ATTORNEY DOCKET NO. | |
|---|--------------------|---------------------------------|---------|--|---------------------|--|
| 09/514,312 | 02/28/00 | KASAI | | ************************************** | 31671-157328 | |
| - | | HM12/1024 | · ¬ [| EXAMINER | | |
| Venables | | I II I de dans y de la desiment | , | DI NOLA BARON, L | | |
| P O Box 343 Washington | 85 DC 20043-999 | 7 8 | [| ART UNIT PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

10/24/00

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| | Application No. | | Applicant(s) | | | | | | |
| Office Action Summer | 09/514,312 | | KASAI ET AL. | ı | | | | | |
| Office Action Summary | Examiner | | Art Unit | | | | | | |
| | Liliana Di Nola-B | aron | 1615 | | | | | | |
| The MAILING DATE of this communication appe Period for Reply | ars on the cover s | heet with the co | respondence ad | ldress | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. | / IS SET TO EXP | IRE <u>3</u> MONTH(S | S) FROM | | | | | | |
| Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communically the period for reply specified above is less than thirty (30) days be considered timely. If NO period for reply is specified above, the maximum statutory communication. Failure to reply within the set or extended period for reply will, by Status | cation. s, a reply within the st period will apply and | atutory minimum of will expire SIX (6) M | thirty (30) days will | ailing date of this | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>28 F</u> | Sobruary 2000 | | | | | | | | |
| · — · · · · · · · · · · · · · · · · · · | s action is non-fir | nal | | | | | | | |
| 3) Since this application is in condition for allowa closed in accordance with the practice under <i>I</i> | nce except for fo | mal matters, pro | | he merits is | | | | | |
| Disposition of Claims | | ٠ | | | | | | | |
| 4)⊠ Claim(s) <u>1-14</u> is/are pending in the application | | | | • | | | | | |
| 4a) Of the above claim(s) is/are withdraw | wn from consider | ation. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | | |
| 6)⊠ Claim(s) <u>1-14</u> is/are rejected. | | | | | | | | | |
| 7)⊠ Claim(s) <u>1-14</u> is/are objected to. | | | | | | | | | |
| 8) Claims are subject to restriction and/or | election requiren | nent. | | | | | | | |
| Application Papers | | | | | | | | | |
| 9) The specification is objected to by the Examine | er. | | | | | | | | |
| 10)⊠ The drawing(s) filed on 28 February 2000 is/are | e objected to by t | ne Examiner. | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved. | | | | | | | | | |
| 12) The oath or declaration is objected to by the Ex | kaminer. | | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | | |
| 13)⊠ Acknowledgment is made of a claim for foreign | priority under 35 | 115 C \$ 110(a) | (d) | | | | | | |
| a) ☑ All b) ☐ Some * c) ☐ None of the CERTIFI | | - ', | • / | | | | | | |
| 1.⊠ received. | icb copies of the | phoney docume | ilis liave beeli. | | | | | | |
| 2.☐ received in Application No. (Series Code | - / Serial Number | • | | | | | | | |
| 3. ☐ received in this National Stage application | | | DCT Bulo 17 2/s | a)) | | | | | |
| * See the attached detailed Office action for a list of | | • | | 1//. | | | | | |
| | | | | | | | | | |
| 14) Acknowledgement is made of a claim for dome | Suc phonty under | , | ∌(e). | | | | | | |
| Attachment(s) | , | | • | | | | | | |
| 15) ⊠ Notice of References Cited (PTO-892) 16) ⊠ Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) ⊠ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 18) | • | r (PTO-413) Paper l Patent Application (f | | | | | | |
| | | 4 | | | | | | | |

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DETAILED ACTION

Claim Objections

1. Claims 1-14 are objected to because of the following informalities: the claims are not written in proper idiomatic English. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 2, 4, 6, 7, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Provonchee et al. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and to a coated material comprising said coating agent.

 Provonchee et al. discloses polysaccharide compositions of the gel-forming beta-1,3-glucan type and methods of preparing and using said polysaccharides (See e.g., col. 1, lines 6-14).

 Provonchee et al. teaches that the beta-1, 3-glucan polysaccharides of the invention are widely distributed in nature as components of yeast cell walls (See e.g., col. 1, lines 15-35). Provonchee et al. describes the Critical Temperature Neutralization (CTN) method for preparing solutions and gels of the invention and teaches that the beta-1, 3-glucan polysaccharides are separated from a culturing method by known methods, heated and the pH of the solution is neutralized by addition of an acid (See e.g., col. 4, lines 4-66). Provonchee et al. teaches that the CTN method makes possible applications such as microencapsulation and formation of biodegradable

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therapeutic agent microcarriers (See e.g., col. 8, lines 53-68). Additionally, Provonchee et al. teaches that the gels of the invention may be used for controlled release of pharmaceuticals, preparation of food and coating of seeds, embryos, plantelets and the like (See e.g., col. 9, lines 1-39).

The compositions and methods disclosed by Provonchee et al. meet the limitations of claims 1, 2, 4, 6, 7, 10, 12 and 13 of the instant application, as they contemplate a coating agent comprising yeast cell wall fractions and a coated material comprising said coating agent. Thus, Provonchee et al. anticipates the claimed invention.

4. Claims 1, 2, 4, 6, 7, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and to a coated material comprising said coating agent.

Shank provides a product, such as a drug, condiment or vitamin, encapsulated within biological capsules provided by microorganisms, such as yeast (See e.g., col. 1, line 46 to col. 2, line 51). Shank teaches that the yeast cell wall may be softened by treatment with proteolytic enzymes, and then hardened with dilute aldehydes (See e.g., col. 5, lines 28-50). In the examples provided, Shank teaches that the encapsulated material is cast upon an acidified paper (See e.g., Examples I-V).

The compositions and methods disclosed by Shank meet the limitations of claims 1, 2, 4, 6, 7, 10, 12 and 13 of the instant application, as they contemplate a coating agent comprising yeast cell wall fractions and a coated material comprising said coating agent. Thus, Shank anticipates the claimed invention.

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Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Provonchee et al., as applied to claims 1, 2, 4, 6, 7, 10, 12 and 13 above, in view of Jamas et al. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and a plasticizer and to a coated material comprising said coating agent.

The teachings of Provonchee et al. have been summarized above. Provonchee et al. does not include a plasticizer in the compositions of the invention.

Jamas et al. provides a composition and method utilizing yeast glucan as a dietary additive and explains that beta-glucans are the alkali-insoluble portion obtained from yeast cell walls (See e.g., col. 3, line 1 to col. 4, line 10). Jamas et al. teaches that the glucans can be treated with hydrolytic enzymes or an acid after extraction from yeast to decrease viscosity and increase water holding capacity (See e.g., col. 5, lines 11-62). Jamas et al. teaches that the dietary additive of the invention can be administered orally, the glucan can be administered alone or with other ingredients and the compositions of the invention can be in the form of tablet or powder and include additives, such as a plasticizer (See e.g., col. 6, line 66 to col. 7, line 20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Provonchee et al., by adding a plasticizer and administer the composition in the form of tablet, as taught by Jamas et al. One of

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ordinary skill in the art would have been motivated to make such a modification to further control the release of the coated material. Because of the teachings of Jamas et al., that beta-glucan may be combined with a plasticizer, one of ordinary skill in the art would have a reasonable expectation that the coating agent claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank in view of Jamas et al. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and a plasticizer and to a coated material comprising said coating agent. The teachings of Shank have been summarized above (See 35 U.S.C. 102(b) rejection to claims1, 2, 4, 6, 7, 10, 12 and 13). Shank does not include a plasticizer in the compositions of the invention. The teachings of Jamas et al. have been summarized above (See 35 U.S.C. 103(a) rejection of claims 1-14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions and methods disclosed by Shank, by adding a plasticizer and administer the composition in the form of tablet, as taught by Jamas et al. One of ordinary skill in the art would have been motivated to make such a modification to further control the release of the coated material. Because of the teachings of Jamas et al., that beta-glucan may be combined with a plasticizer, one of ordinary skill in the art would have a reasonable expectation that the coating agent claimed in the instant application would be

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successful. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Friday, 6:30AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/1235.

October 20, 2000